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10/507,347

01/11/2006

Thiemo Arnim Blank

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EXAMINER

NEAL, TIMOTHY J

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

10/17/2007

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/507,347

Applicant(s)

BLANK, THIEMO ARNIM

Examiner

Timothy J. Neal

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2007.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-59 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 24-59 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 5/07;7/07.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This action is in response to the Remarks and IDS filed on 5/29/2007.

#### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the meanders and "S" shape of the bridges, the frusto-conical shape of the male-female form-fitting portions, and the bridges having a longitudinal axis that is not parallel to the longitudinal axis of the structure must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The rings are "S" shaped and include meanders, but the bridges are not shown as including any such structure.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New

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Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

**Claims 25-59** are objected to because of the following informalities: claims 25 and 44 state "at least one bridge exhibits reduced electrical conductivity throughout" without clearly stating what the reduced conductivity is compared with. If the bridge conductivity is reduced compared to the strut conductivity, the claim should refer to this difference. If the bridge conductivity is reduced over time, this should be stated. The claim should be clarified to avoid any 112 rejections. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 25-30, 32-34, 36, 37, 41, 43, 44, 48, and 53** are rejected under 35 U.S.C. 102(b) as being anticipated by Fogarty et al. (US 6,123,722) as evidenced by Frantzen (US 5,741,327).

Fogarty discloses a stent having a plurality of rings (112) having struts (Figure 12C) and bridge struts on adjacent rings (Figure 12A). There are other embodiments

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that read on the independent claims (see figure 14 for example). The bridge struts are inter-engaging male/female portions (Figure 12A). The stent is nitinol (Column 19 Line 45).

Fogarty discloses the invention substantially as claimed as stated above.

Fogarty does not explicitly disclose a conductivity-reducing layer on an abutment surface of at least one of the complementary mating portions; a portion in which the chemical composition of said metal structure is modified; an oxide layer. However, Frantzen teaches that an oxide layer forms on a nickel titanium stent when the stent is formed (Column 7 Line 61). Therefore, the Fogarty's stent includes the conductivity-reducing layer claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 31, 38-40, and 42** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty '722 in view of Frantzen (US 5,741,327).

Fogarty discloses the invention substantially as claimed as stated above.

Fogarty does not explicitly disclose the use of an adhesive with the embodiment shown in figure 12C or the stent being stainless steel or the meander/"S" shape of the rings.

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Frantzen teaches using an adhesive to connect two bridges (Figs 7-19; Col 7 line 37 – Col 11 line 13) and using stainless steel (Column 1 Lines 52-53) and the shapes of the rings (Figure 1). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Fogarty's bridges to include Frantzen's adhesive and stainless steel and shape. Such a modification would provide a means for securing the bridges and rings to each other. Also, stainless steel is a well-known material for stents and is a known variant to nitinol. The shapes of the rings increase flexibility.

**Claims 35 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty '722 in view of Leonhardt (WO.99/43378).

Fogarty discloses the invention substantially as claimed as stated above. Fogarty does not explicitly disclose the bridge struts comprising a sleeve. Leonhardt teaches the use of a sleeve to secure portions of stents to each other (Page 6 lines 6-9; fig 2D). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Fogarty's bridges to include Leonhardt's sleeve. Such a modification would provide a means to connect the portions of the device securely to each other.

**Claims 45-47 and 50-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty '772.

Fogarty discloses the invention substantially as claimed as stated above.

Fogarty does not explicitly disclose the mounting and laser cutting of the workpiece. However, the Examiner considers it old and well known in the art to mount a tubular structure on a support such as a mandrel, and then to use a laser to cut the pattern of the stent. When a laser is used to create the bridge structure, especially the frusto-conical sections, it would be within the purview of one having ordinary skill to depart the laser from the longitudinal axis. This is necessary to create the desired shape. As suggested in Frantzen, (see above), and in the Applicant's disclosure, the use of a laser is generally sufficient to create an oxide layer that will insulate the bridge struts from each other. Also, it is known in the art to apply oxidizing agents to stents to prevent restonsis (see Hastings et al. US 5,951,458 in relevant prior art). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Fogarty's method to include the laser cutting technique. Such a modification provides a means for producing the stent with a high degree of accuracy and precision.

**Claims 54 and 59** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty '772 in view of Kim (US 6,270,524).

Fogarty discloses the invention substantially as claimed as stated above.

Fogarty does not explicitly disclose pins for connecting the bridge struts. Kim teaches pins to connect adjacent rings (112). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Fogarty's

bridges to include Kim's pins. Such a modification would secure the bridges to each other while allowing some degree of flex.

**Claims 55-58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogarty '772 in view of Kim (US 6,270,524) further in view of Pacetti (US 6,712,844).

Fogarty and Kim disclose the invention substantially as claimed as stated above. They do not explicitly disclose the pin being made of electrically insulating material. Pacetti teaches the use of non-conducting materials to connect bridges in order to improve the MRI image of the stent (Column 7 Lines 4-26). Ceramics and oxide layers are known insulating materials and would have been obvious based on Pacetti's teaching. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify Fogarty and Kim's pins to include Pacetti's insulating material. Such a modification would improve the MRI of the stent.

### ***Response to Arguments***

Applicant's arguments with respect to claims 25-59 have been considered but are moot in view of the new ground(s) of rejection.

First, the rejection is made final because the rejection of the independent claims is based on art found on IDS's submitted after the Non-Final Rejection. The arguments are directed to a reference no longer relied upon, but the Examiner will address the issues the Applicant raised. The Examiner considers Fogarty to clearly disclose rings linked by bridge struts. As a note, the Examiner does not consider the term "reduced"



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to exclude an element with no conductivity. The conductivity could be "reduced" to zero. See the Objection above, but the Examiner thinks further language is necessary to clarify the Applicant's position regarding that particular limitation. All other arguments were directed to deficiencies in the no longer applicable prior art.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hastings et al. US 5,951,458 shows oxidizing agents on stents for preventing restenosis.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 5/29/2007, Fogarty et al. (US 6,123,722) prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Neal whose telephone number is (571) 272-0625. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TJN

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
10/12/07